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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,038	02/27/2002	James R. Komorowski	NUTRI.023A	6775

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/090,038

Applicant(s)

KOMOROWSKI ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 23-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 23-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20, 23-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066), each in view of de la Harpe et al. (US Pat. 5,948,772) and Brand-Miller for the reasons of record set forth in the prior Office Action and the further reasons below.

McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066) were discussed in the prior Office Action and the same are incorporated herein.

de la Harpe et al., Jensen and Brand-Miller were discussed in the prior Office Action and the same are incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references.

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Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Applicant argues that there is no discussion as to effects of biotin on serum lipid levels. However, the prior art discloses that due to ineffective insulin and compromised glucose metabolism in diabetics, the body must rely on lipid metabolism to meet its energy requirements resulting in hypercholesterolemia (De La Harpe, Column 1, lines 24-36). Biotin is disclosed to improve insulin function and reduce glucose levels (McCarty '401, Column 1, lines 54-68, Column 2, lines 1-16; McCarty '066, Column 1, lines 59-68, Column 2, lines 1-21). Thus, the body would not be required to rely on lipid metabolism. As such, one of ordinary skill in the art would expect that biotin would have a beneficial effect on hypercholesterolemia, and, thus, would be useful for treatment of dyslipidemia.

In response to Applicant's argument that the use of chromium and biotin to specifically target post-prandial hyperglycemia is not disclosed by any of the references, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Contrary to Applicant's arguments, McCarty does disclose that administration of chromium resulted in reduction of postprandial glucose levels (McCarty '401, Column 1, lines 47-53; McCarty '066, Column 1, lines 52-58). Further, one of the major goals of diabetes therapy is to normalize the blood glucose profile, including both fasting and postprandial glucose concentrations (Brand Miller, Pg. 747S). As such, one of ordinary skill would have been motivated to use both chromium and biotin with the expectation that the blood glucose profile

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would be normalized. The fact that Applicant has recognized that biotin is also effective in targeting post-prandial hyperglycemia in addition to fasting glucose levels, in light of the above, does not overcome the rejection herein.

Applicant argues that the administration of chromium and biotin to a foodstuff to lower the food's glycemic index (GI) are not disclosed or suggested by any of the references. However, the use of chromium and biotin for treatment of diabetes is disclosed by the prior art. As indicated above, the goal of diabetes therapy is to normalize the blood glucose profile, including fasting and postprandial glucose concentrations. Further, it is disclosed that meals for individuals with diabetes should emphasize low-GI foods, i.e. foods that produce minimal fluctuations in blood glucose (Brand Miller, Pg. 747S). In light of the above, one of ordinary skill in the art would be motivated to add chromium and biotin to the food with the expectation that the diabetic's blood glucose profile would be normalized by eating the food. Further, since chromium is disclosed to reduce postprandial glucose levels, one of ordinary skill in the art would expect that eating chromium enriched foods would result in lower fluctuations in blood glucose; thus, according to the definition above, the GI of the food would be lower. The fact that Applicant has recognized that biotin is also effective in lowering the GI of food, in light of the above, does not overcome the rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

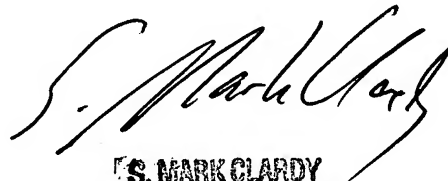
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

October 30, 2003



S. MARK CLARDY
PATENT EXAMINER
GROUP 1200

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